

| | | | |
|--|---|--------------------------------------|-----------------------------------|
| FORM PTO-1449/A and B (Modified) | | APPLICATION NO.: 10/618,884 | ATTY. DOCKET NO.: N0260.70058US00 |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | FILING DATE: July 14, 2003 | CONFIRMATION NO.: 5880 |
| | | APPLICANT: Victor E. Shashoua et al. | |
| | | GROUP ART UNIT: 1614 | EXAMINER: Donna A. Jagoe |
| Sheet | 1 | of | 1 |

U.S. PATENT DOCUMENTS

| Examiner's Initials | Cite No. | U.S. Patent Document | | Name of Patentee or Applicant of Cited Document | Date of Publication or of issue of Cited Document MM-DD-YYYY |
|---------------------|----------|----------------------|-----------|---|---|
| | | Number | Kind Code | | |
| | | 5,952,317 | | Deluca, et al. | 09-14-1999 |
| | | 5,976,784 | | DeLuca, et al. | 11-02-1999 |
| | | | | | |

FOREIGN PATENT DOCUMENTS

| | | | | | | | |
|--|--|----|----------|----|--------------------------------------|------------|--|
| | | WO | 97/11053 | A1 | Wisconsin Alumni Research Foundation | 03-27-1997 | |
| | | | | | | | |

OTHER ART — NON PATENT LITERATURE DOCUMENTS

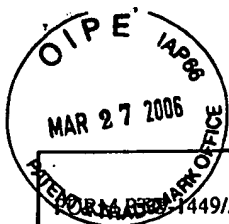
| Examiner's Initials | Cite No. | Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published. | Translation (Y/N) | |
|---------------------|----------|---|-------------------|--|
| | | | | |
| | | | | |
| | | | | |

| | |
|-----------|---------------------------|
| EXAMINER: | DATE CONSIDERED: 10/12/06 |
|-----------|---------------------------|

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

* a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. __, filed __, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

[NOTE — No copies of U.S. patents, published U.S. patent applications, or pending, unpublished patent applications stored in the USPTO's Image File Wrapper (IFW) system, are included. See 37 CFR §1.98 and 1287OG163. Copies of all other patent(s), publication(s), unpublished, pending U.S. patent applications, or other information listed are provided as required by 37 CFR §1.98 unless 1) such copies were provided in an IDS in an earlier application that complies with 37 CFR §1.98, and 2) the earlier application is relied upon for an earlier filing date under 35 U.S.C. §120.]



| | | | | | | | |
|--|---|----|---|--------------------------------------|--|-----------------------------------|--|
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | | | APPLICATION NO.: 10/618,884 | | ATTY. DOCKET NO.: N0260.70058US00 | |
| | | | | FILING DATE: July 14, 2003 | | CONFIRMATION NO.: 5880 | |
| | | | | APPLICANT: Victor E. Shashoua et al. | | | |
| | | | | GROUP ART UNIT: 1614 | | EXAMINER: Donna A. Jagoe | |
| Sheet | 1 | of | 7 | | | | |

U.S. PATENT DOCUMENTS

| Examiner's Initials | Cite No. | U.S. Patent Document | | Name of Patentee or Applicant of Cited Document | Date of Publication or of issue of Cited Document MM-DD-YYYY |
|------------------------|-------------|----------------------|--------------|--|--|
| | | Number | Kind Code | | |

| | | | | |
|---|-----------|----|-------------------|------------|
| * | 3,539,573 | | Schmutz | 11/10/1970 |
| * | 3,621,048 | | Bauman | 11/16/1971 |
| * | 4,097,597 | | Horrom, et al. | 06/27/1978 |
| * | 4,218,234 | A | Nadasy, et al. | 08/19/1980 |
| * | 4,346,085 | | Growdon, et al. | 08/24/1982 |
| * | 4,351,831 | | Growden, et al. | 09/28/1982 |
| * | 4,550,109 | | Folkers, et al. | 10/29/1985 |
| * | 4,554,272 | | Bock, et al. | 11/19/1985 |
| * | 4,558,049 | | Bernardi, et al. | 12/10/1985 |
| * | 4,684,646 | | Chang, et al. | 08/04/1987 |
| * | 4,868,161 | | E. Roberts | 09/19/1989 |
| * | 4,902,505 | | Pardridge, et al. | 02/20/1990 |
| * | 4,933,324 | | Shashoua | 06/12/1990 |
| * | 4,939,174 | | Shashoua | 07/03/1990 |
| * | 5,169,762 | | Grey, et al. | 12/08/1992 |
| * | 5,284,876 | | Shashoua | 02/08/1994 |
| * | 5,532,372 | | Saji, et al. | 07/02/1996 |
| * | 5,532,374 | | Lee, et al. | 07/02/1996 |
| * | 5,545,719 | | Shashoua | 08/13/1996 |
| * | 5,603,959 | A1 | Horrobin, et al. | 02/18/1997 |
| * | 5,604,198 | | Poduslo, et al. | 02/18/1997 |
| * | 5,646,180 | | Chaturvedi | 07/18/1997 |
| * | 5,824,701 | A | Greenwald et al. | 10/20/1998 |
| * | 5,827,819 | | Yatvin, et al. | 10/27/1998 |
| * | 5,955,459 | | Bradley, et al. | 09/21/1999 |
| * | 6,005,004 | | Katz et al. | 12/21/1999 |
| * | 6,024,977 | | Yatvin et al. | 02/15/2000 |
| * | 6,107,499 | | Shashoua | 08/22/2000 |
| * | 6,245,811 | B1 | Horrobin et al. | 06/12/2001 |
| * | 6,407,075 | B1 | Scott et al. | 06/18/2002 |
| * | 6,407,137 | B2 | Shashoua | 06/18/2002 |
| * | 6,448,392 | B1 | Hostetler et al. | 09/10/2002 |
| * | 6,576,636 | B2 | Webb et al. | 06/10/2003 |
| * | 6,602,902 | B2 | Shashoua et al. | 08/05/2003 |
| * | 6,627,601 | B2 | Shashoua | 09/30/2003 |

| | | | | | | | |
|--|---|----|---|--------------------------------------|--|-----------------------------------|--|
| FORM PTO-1449/A and B (Modified) INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | | | APPLICATION NO.: 10/618,884 | | ATTY. DOCKET NO.: N0260.70058US00 | |
| | | | | FILING DATE: July 14, 2003 | | CONFIRMATION NO.: 5880 | |
| | | | | APPLICANT: Victor E. Shashoua et al. | | | |
| | | | | GROUP ART UNIT: 1614 | | EXAMINER: Donna A. Jagoe | |
| Sheet | 2 | of | 7 | | | | |

FOREIGN PATENT DOCUMENTS

| Examiner's Initials | Cite No. | Foreign Patent Document | | | Name of Patentee or Applicant of Cited Document (not necessary) | Date of Publication of Cited Document MM-DD-YYYY | Translation (Y/N) |
|------------------------|-------------|-------------------------|-----------|--------------|---|---|--------------------------|
| | | Office/ Country | Number | Kind Code | | | |
| | * | AU | 770519 | | Protarga, Inc. | 04/05/2001 | |
| | * | AU | 746472 | | Protarga, Inc. | 06/15/1999 | |
| | * | DE | 24 56 947 | A1 | Pfizer, Inc. | 06/12/1975 | With English Abstract |
| | * | DE | 29 32 869 | A1 | Ciba-Geigy AG | 02/28/1980 | |
| | * | EP | 0909183 | B1 | Protarga, Inc. | 04/21/1999 | |
| | * | EP | 0 599 576 | A1 | Scotia Holding, PLC | 06/01/1994 | |
| | * | EP | 0 311 100 | A2 | F. Hoffman | 04/12/1989 | |
| | * | EP | 0 091 694 | A1 | Eisai Co., Ltd. | 10/19/1983 | |
| | * | EP | 0909183 | B1 | Protarga, Inc. | 08/11/2004 | |
| | * | EP | 0 035 375 | A1 | Takeda Yakuhin Kogyo Kabushiki Kaisha | 09/09/1981 | |
| | * | EP | 0 761 644 | A | Kao Corporation | 03/12/1997 | |
| | * | FR | 2 592 883 | A | Ire Celltarg SA | 07/17/1987 | |
| | * | JP | 75-9469 | | New OJI Paper Co., Ltd | 07/29/1976 | Abstract |
| | * | JP | 8245378 | A | Sagami Chem Res Centerfuji Yakuhin:KK | 09/24/1996 | Abstract |
| | * | JP | 7082146 | | Sagami Chem Res Center | 03/28/1995 | Abstract |
| | * | JP | 6072868 | | Maruha Corp. | 03/15/1994 | Abstract |
| | * | JP | 61204136 | | Teijin Ltd. | 09/10/1986 | Abstract |
| | * | JP | 10168047 | A | Kao Corp | 06/23/1998 | Abstract |
| | * | JP | 2256624 | A | Sagami Chem Res Centre | 10/17/1990 | Abstract |
| | * | JP | 55053208 | A | Mitsubishi Chem Ind. Ltd. | 04/18/1980 | Abstract |
| | * | SU | 477159 | A | Phytopathology Inst. | 10/14/1976 | Abstract |
| | * | WO | 02/087586 | A1 | Control Delivery Systems, Inc. | 11/07/2002 | |
| | * | WO | 01/62085 | A1 | Medinox, Inc. | 08/30/2001 | |
| | * | WO | 00/01417 | | Cyclacel Limited | 01/13/2000 | |
| | * | WO | 00/53231 | | Protarga, Inc. | 09/14/2002 | |
| | * | WO | 00/67802 | | Protarga, Inc. | 11/16/2002 | |
| | * | WO | 98/09621 | | Scotia Holdings, PLC | 04/12/1998 | |
| | * | WO | 99/26620 | | Neuromedia, Inc. | 06/03/1999 | |
| | * | WO | 99/44600 | | Scotia Holding, PLC | 09/10/1999 | |
| | * | WO | 89/07938 | | Shashoua | 09/08/1989 | |
| | * | WO | 98/17325 | | Oregon Health Sciences University | 04/30/1998 | |
| | * | WO | 97/33173 | A | The Regents of the University of California | 09/12/1997 | |
| | * | WO | 96/34855 | | Scotia Holding PLC | 11/7/1996 | |
| | * | WO | 96/22303 | | Commonwealth of Scientific and Industrial Research | 07/25/1996 | |

| | | | | | | | |
|--|---|----|---|--------------------------------------|--|-----------------------------------|--|
| FORM PTO-1449/A and B (Modified) INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | | | APPLICATION NO.: 10/618,884 | | ATTY. DOCKET NO.: N0260.70058US00 | |
| | | | | FILING DATE: July 14, 2003 | | CONFIRMATION NO.: 5880 | |
| | | | | APPLICANT: Victor E. Shashoua et al. | | | |
| | | | | GROUP ART UNIT: 1614 | | EXAMINER: Donna A. Jagoe | |
| Sheet | 3 | of | 7 | | | | |

FOREIGN PATENT DOCUMENTS

| | | | | | |
|---|----|-----------|----|---|------------|
| * | WO | 96/04001 | | Molecular/Structural Biotechnologies, Inc. | 02/15/1996 |
| * | WO | 85/00520 | | The McLean Hospital Corp. | 04/06/1989 |
| * | WO | 02/087586 | A1 | Control Delivery Systems, Inc. | 11/07/2002 |
| * | WO | 92/06089 | A | H. Lundbeck | 04/16/1992 |
| * | WO | 98/32718 | A | Norsk Hydro | 07/30/1998 |
| * | WO | 98/43994 | A | Genzyme Corporation | 10/08/1998 |
| * | WO | 93/1168 | | Schering Aktiengesellschaft Berling Underbergkamen | 06/24/1993 |

OTHER ART — NON PATENT LITERATURE DOCUMENTS

| Examiner's Initials | Cite No | Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published. | Translation (Y/N) |
|------------------------|------------|--|----------------------|
| | * | AIHARA, M. et al., "Effects of liposteroid on skin lesions in autoimmune MRLlpr/lpr mice," <i>Journal of Dermatological Science</i> , 16, 1997, pp. 45-51. | |
| | * | FUNAUCHI, M. et al., "Effects of liposteroid on the hemophagocytic syndrome in systemic lupus erythematosus," <i>Lupus</i> , 12, 2003, pp. 483-485. | |
| | * | HAZARD Database, "Chemical Teratogens, Carcinogens, Mutagens: Dexamethasone palmitate," http://www.evol.nw.ru/labs/lab38/spirov/hazard/dexamethasone_palmitate.html , printed from website on August 31, 2004. | |
| | * | HOSHI, K. et al., "Double-Blind Study with Liposteroid in Rheumatoid Arthritis," <i>Drugs Exptl. Clin. Res.</i> , XI(9), 1985, pp. 621-626. | |
| | * | KARMALI, R.A., et al., "Effect of Omega-3 Fatty Acids on Growth of a Rat Mammary Tumor," <i>J Nail Cancer Inst.</i> , 73(2), 1984, pp. 457-461. (Abstract) | |
| | * | MIZUSHIMA, Y. et al., "Tissue distribution and anti-inflammatory activity of corticosteroids incorporated in lipid emulsion," | |
| | * | UEDA et al., "Synthesis and Antitumor Evaluation of 2'-Oxycarbonylpaclitaxels (Paclitaxel-2'-Carbonates)," <i>Bioorganic & Medicinal Chemistry Letters</i> , Vol. 4, No. 15, 1994, pp. 1861-1864. | |
| | * | YAMATSU et al., "Polyprenyl Carboxylic Acid Amides," <i>Chemical Abstracts</i> , Vol. 100, No. 19 issued 7 May 1984, p. 555, Abstract No. 156839z, EP91, 694, dated 19 October 1983. | |
| | * | YOKOYAMA, K. et al., "Development of a Corticosteroid Incorporated in Lipid Microspheres (Liposteroid)," <i>Drugs Exptl. Clin. Res.</i> , XI(9), 1985, pp. 611-620. | |
| | * | "Cytosar-U cytarabine for injection, USP," Product insert, 2/2002. | |
| | * | "Dexamethasone palmitate: Chemical Teratogens, Carcinogens, Mutagens," CAS# [33755-46-3], ACX# [11012259], http://www.evol.nw.ru/labs/lab38/spirov/hazard/dexamethasone_palmitate.html | NO DATA |
| | * | AIHARA, M., et al., "Effects of liposteroid on skin lesions in autoimmune MRLlpr/lpr mice," <i>J. of Dermatological Science</i> 16 (1997), pp. 45-51. | |
| | * | ALTHAUS, I.W. et al., "The amphiphilic properties of novenamides determine their activity as inhibitors of HIV-1 RNase H," <i>Experientia</i> , Vol. 52, 1996, pp. 329-335, XP008039697. | |
| | * | ATTARD, George S., et al., "Phase behaviour of novel phospholipid analogues," <i>Chemistry and Physics of Lipids</i> , vol. 76, 1995, pages 41-48. | |
| | * | BALDESSARINI, et al., "Dopamine and Pathophysiology of Dyskinesia...", <i>Ann. Rev. Neurosci.</i> 3:23-41 (1980). | |
| | * | BOLWELL, et al., "High dose cytarabine: a review," <i>Leukemia</i> 5 (5/1988), pp. 253-60 Abstract. | |

| | | | | | | | |
|----------------------------------|---|----|---|--|--|-----------------------------------|--|
| FORM PTO-1449/A and B (Modified) | | | | APPLICATION NO.: 10/618,884 | | ATTY. DOCKET NO.: N0260.70058US00 | |
| | | | | FILING DATE: July 14, 2003 | | CONFIRMATION NO.: 5880 | |
| | | | | APPLICANT: Victor E. Shashoua et al. | | | |
| | | | | GROUP ART UNIT: 1614 | | EXAMINER: Donna A. Jagoe | |
| Sheet | 4 | of | 7 | INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | | |

OTHER ART — NON PATENT LITERATURE DOCUMENTS

| | | | | |
|--|---|---|--|--|
| | * | BRIDGES, A.J. et al., "N ⁶ -(2,2-Diphenylethyl)adenosine, a Novel Adenosine Receptor Agonist with Antipsychotic-like Activity", <i>J. Med. Chem.</i> 30:1709-1711 (1987) | | |
| | * | BRUTOVSKA, A. et al., "Isothiocyanates and Their Synthetic Producers. VIII. The Synthesis and the Study of Spectral Features of Substituted Monothiourethanes," <i>Chem. Zvesti</i> , vol. 23, 1969, pp. 736-741. | | |
| | * | DATABASE BEILSTEIN, <i>Beilstein Institute for Organic Chemistry</i> , Frankfurt-Main, DE, 29 June 1989, XP002311506, Database accession no. 2146750 (BRN). | | |
| | * | DATABASE BEILSTEIN, <i>Beilstein Institute for Organic Chemistry</i> , Frankfurt-Main, DE, 15 February 1990, XP002311507, Database accession no. 3166362 (BRN). | | |
| | * | DATABASE BEILSTEIN, <i>Beilstein Institute for Organic Chemistry</i> , Frankfurt-Main, DE, 29 June 1989, XP002311508, Database accession no. 2270240 (BRN). | | |
| | * | DATABASE BEILSTEIN: 29 June 1989 (1989-06-29), XP002329550; Database accession no. 2199386 (BRN), Abstract & SU 477 159 A (STREL'TSOV, BLIZNYUK) 1976 | | |
| | * | DATABASE HCAPLUS ACS, 6 September 1991, XP002311505, retrieved from STN, Database accession no. 115:91935/DN, RN 2411-58-7, 135346-35-9, 7418-03-3. | | |
| | * | DATABASE HCAPLUS ACS: 11 October 2000 (2000-10-11); XP002329554; Retrieve from STN Database accession no. 134:193273/DN, Abstract, RN327082-01-9; & CHEN, ZAI-XIN ET AL: ZHONGGUO YIYAO GONGYE ZAZHI BIANJIBU, vol 31, no. 6, 2000, pages 265-268 | | |
| | * | DATABASE HCAPLUS ACS: 12 May 1984 (1984-05-12); XP002329551; Retrieved from STN Database accession no. 93:90207/DN; Abstract, RN52067-53-5, 74551-09-0 & JP 55 053208 A (Mitsubishi Chemical Ind. Co.); 18 April 1980 (1980-04-18) | | |
| | * | DATABASE HCAPLUS ACS: 2 July 1998 (1998-07-02); XP002329553; Retrieved from STN Database accession no. 129:135899/DN, Abstract, RN210540-30-0, -31-1 & JP 10 168047 A (KAO Corp.), 23 June 1998 (1998-06-23) | | |
| | * | DATABASE HCAPLUS ACS: 28 June 1991 (1991-06-28); XP002329552; Retrieved from STN Database accession no. 114:254032, Abstract, RN29271-27-0, 49802-20-2, 134036-50-3 & JP 02 256624 A (Sagami Chemical Research Center) 17 October 1990 (1990-10-17) | | |
| | * | DeVITA, JR., et al., <i>Cancer Principles & Practice of Oncology</i> , 5 th Ed., pp. 443-444. 1997 | | |
| | * | DHOPESHWARKER, G., "Fatty Acid Transport Through the Blood-Brain Barrier.", <i>Biochim Biophys. Acta</i> 255:572-579. | | |
| | * | Domagala, John M., et al., "New Class of Anti-HIV-1 Agents Targeted Toward the Nucleocapsid Protein NCp7: The 2,2-Dithiobisbenzamides." <i>Bioorganic & Medicinal Chemistry</i> , Vol. 5, No. 3, pages 569-579 (1997). | | |
| | * | FUNAUCHI, M., et al., "Effects of liposteroid on the hemophagocytic syndrome in systemic lupus erythematosus," <i>Lupus</i> 12 (2003), pp. 483-485. | | |
| | * | GARZON-ABURBEH, et al., "A Lymphotropic Product of L-Dopa: Synthesis" <i>J. Med. Chem.</i> 29: 687-691 (1986) | | |
| | * | GUÉNARD, et al., "Effects of the Hydrophobicity of Taxoids on their Interaction with Tubulin", <i>Bioorganic & Medicinal Chemistry</i> Vol. 8, (2000) pp. 145-156. | | |
| | * | GUFFY, M.M., et al., "Effect Of Cellular Fatty Acid Alteration On Adriamycin Sensitivity In Cultured L1210 Murine Leukemia Cells", <i>Cancer Res.</i> (1984), 44:1863-1866. | | |
| | * | GUILLONNEAU, C. et al., "Synthesis of 9- O-Substituted Derivatives of 9-Hydroxy-5,6-dimethyl-6H-pyrido[4,3-b]carbazole-1-carboxylic Acid (2-(Dimethylamino)ethyl)amide and Their 10- and 11-Methyl Analogues with Improved Antitumor Activity," <i>J. Med. Chem.</i> 1999, 42, pp. 2191-2203, XP-002311501. | | |
| | * | GUNNE, et al., "Oral Dyskinesia in Rats Following Brain Lesions and Neuroleptic Drug Administration", <i>Psychopharmacology</i> 77:134-139 (1982) | | |
| | * | HAAS, et al., "Effektivität intramuskulär verabreichten Cytosin-Arabinosids bei der ambulanten Behandlung von Kindern mit akuter Leukämie in Remission," <i>Onkology</i> (2/1980) pp. 53-57. (English summary included). | | |
| | * | HESSE, et al., "Uptake in brain neurophysiological activity of two lipid esters of gamma-aminobutyric acid" <i>Neuropharmacol.</i> 27:6:637-40 (1988). | | |
| | * | HO, et al., "Pharmacologic Studies of Cyclocytidine and Arabinosylcytosine in Dogs," <i>Drug Metabolism and Disposition</i> 3(4) (1975), pp. 309-313. | | |

| | | | | | | | |
|--|---|----|---|--------------------------------------|--|-----------------------------------|--|
| FORM PTO-1449/A and B (Modified) INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | | | APPLICATION NO.: 10/618,884 | | ATTY. DOCKET NO.: N0260.70058US00 | |
| | | | | FILING DATE: July 14, 2003 | | CONFIRMATION NO.: 5880 | |
| | | | | APPLICANT: Victor E. Shashoua et al. | | | |
| | | | | GROUP ART UNIT: 1614 | | EXAMINER: Donna A. Jagoe | |
| Sheet | 5 | of | 7 | | | | |

OTHER ART — NON PATENT LITERATURE DOCUMENTS

| | | | | |
|--|---|---|---------------|---|
| | * | HO, et al., "Pharmacology of 5'-Esters of 1-β-D-Arabinofuranosylcytosine," <i>Cancer Research</i> 37 (6/1977), pp. 1640-1643. | | |
| | * | HONG, C.I. et al., "Synthesis and Biological Activity of N ⁶ -(n-Alkylureido)purine Ribonucleosides and Their 5γ-Phosphates," <i>J. Pharm. Sci.</i> , Vol. 67, No. 4, April 1978, pp. 569-571, XP008039688. | | |
| | * | HOSHI, K., et al., "Double-blind study with liposteroid in rheumatoid arthritis," <i>Drugs Exptl. Clin. Res.</i> XI(9) (1985), pp. 621-626. | | |
| | * | International Search Report in PCT/US02/09389, mailed February 10, 2004 | | |
| | * | JACOB, et al., "Alpha-Aminobutyric Acid Esters.3. Synthesis, brain uptake and pharmacological properties of C-18 Glyceryl lipid esters of BAGA with varying degree of unsaturation," <i>J. Med. Chem.</i> 30:1573-6 (1987). | | |
| | * | JACOB, et al., "Synthesis, brain uptake and pharmacological properties of a glyceryl lipid containing GABA and the GABA-T inhibitor, gamma-vinyl-GABA," <i>J. Med. Chem.</i> 33:733-6 (1990). | | |
| | * | Janusz, John J., et al., "Vanilloids. 1. Analogs of Capsaicin with Antinociceptive and Antiinflammatory Activity," <i>J. Med. Chem.</i> , Vol. 36, No. 18, pages 2595-2604 (1992). | | |
| | * | Kageyama, Yuichi, et al., "Novel approaches to prodrugs of anticancer diaminodichloroplatinum(II) complexes activated by stereoselective enzymatic ester hydrolysis," <i>Journal of Inorganic Biochemistry</i> , Vol. 70, pp. 25-32 (1998). | | |
| | * | Kalgutkar, Amit S., et al., "Ester and Amide Derivatives of the Nonsteroidal Antiinflammatory Drug, Indomethacin, as Selective Cyclooxygenase-2 Inhibitors," <i>Journal of Medicinal Chemistry</i> , pages 2860-2870 (2000) | | |
| | * | Kariko, Katalin, et al, "n-DECYL-NHpppA2γ p5γ A2γ p5γ A A Phosphatase-Resistant, Active pppA2γp5γ A2γ p5γ A Analog," <i>Biochemical and Biophysical Research Communications</i> , Vol. 128, No. 2, pp. 695-698 (1985). | | |
| | * | KATAOKA, et al., "Effect and Mode of Action of N ⁶ -Behenoyl-β-D-Arabinofuranosylcytosine," <i>Recent Results in Cancer Research</i> 70 (1980), pp. 147-151. | | |
| | * | KONIGSTORFER et al., "Biosynthesis of Ependymins from Goldfish Brain", <i>J. Biol. Chem.</i> , vol. 264 (23): 13689-13692 (1989). | | |
| | * | KONIGSTORFER et al., "Molecular Characterization Of An Ependymin Precursor from Goldfish Brain", <i>J. Neurochem.</i> , 52:310-312 (1989). | | |
| | * | KRISTIAN et al., "Isothiocyanates and Their Synthetic Producers. X. Synthesis of 3-Substituted 2-Thioxo-4-Oxo-3,4-Dihydro-2H-1,3-Benzoxazines," <i>Collect. Czech. Chem. Commun.</i> , vol. 37, 1972, pp. 2972-2974. | | |
| | * | LEE, HEEJOO et al., "Syntheses of 5-Fluorouracil-Fat Conjugates and Evaluation of Their <i>in vitro</i> Cytotoxic Activity," <i>Yakhak Hoechi</i> , vol. 34, 1990, pp. 395-400. | Abstract only | N |
| | * | LENNARTZ, <i>Chem. Ber.</i> , vol. 75, 1942, pp. 833-842. | | N |
| | * | LEONARD, et al., "Identification and Characterization of mRNAs Regulated by Nerve Growth Factor in PC12 Cells", <i>Molecular and Cellular Biology</i> , 7(9):3156-67 (1987) | | |
| | * | LIU, J. et al., "New Approaches for the Preparation of Hydrophobic Heparin Derivatives," <i>J. of Pharmaceutical Sciences</i> , Vol. 83, No. 7, July, 1994, pp. 1034-1039, XP008038024. | | |
| | * | LOHR, et al., "Neuroleptic-Induced Movement Disorders...", <i>Psychiatry</i> , Vol. 3, 1-16 (1989). | | |
| | * | MARDER, S.R., <i>J. Clin. Psychiatry</i> (supp 3), <i>Management of Schizophrenia</i> 57:9-13 (1996) | | |
| | * | McGuigan, C. et al., "Phosphoramidates as potent prodrugs of anti-HIV nucleotides: studies in the amino region." <i>Antiviral Chemistry & Chemotherapy</i> , Vol. 7, No 1, pp. 31-36 (1996). | | |
| | * | McGuigan, C., et al., "Synthesis and Evaluation of some masked phosphate esters of the anti-herpesvirus drug 882C (netivudine) as potential antiviral agents." <i>Antiviral Chemistry & Chemotherapy</i> , Vol. 9, pp. 233-243 (1998). | | |
| | * | MEIER et al., "Molecular Cloning of Bovine and Chick Nerve Growth (NGF) ...", <i>The EMBO Journal</i> , vol. 5, 7:1489-1493 (1986). | | |

| | | | | | |
|--|---|----|---|--------------------------------------|-----------------------------------|
| FORM PTO-1449/A and B (Modified) INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | | | APPLICATION NO.: 10/618,884 | ATTY. DOCKET NO.: N0260.70058US00 |
| | | | | FILING DATE: July 14, 2003 | CONFIRMATION NO.: 5880 |
| | | | | APPLICANT: Victor E. Shashoua et al. | |
| | | | | GROUP ART UNIT: 1614 | EXAMINER: Donna A. Jagoc |
| Sheet | 6 | of | 7 | | |

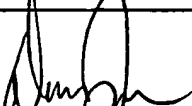
OTHER ART — NON PATENT LITERATURE DOCUMENTS

| | | | | |
|--|---|---|--|--|
| | * | MEYER, K. L. et al., "In Vitro Evaluation of Phosphocholine and Quaternary Ammonium Containing Lipids as Novel Anti-HIV Agents," <i>J. Med. Chem.</i> 1991, 34, pp. 1377-1383, XP-002311504. | | |
| | * | Miroshnikova, Olga V., et al., "Structure-Activity Relationship in the Series of Eremomycin Carboxamides." <i>The Journal of Antibiotics</i> , Vol. 53, No. 3, pp. 286-293 (2000). | | |
| | * | MIZUSHIMA, Y., et al., "Tissue distribution and anti-inflammatory activity of corticosteroids incorporated in lipid emulsion," <i>Annals of the Rheumatic Diseases</i> , 41 (1982), pp. 263-267. | | |
| | * | Nicolaou, Anna, et al., "Synthesis and Properties of Novel Lipopeptides and Lipid Mimetics." <i>Journal of Peptide Science</i> , Vol. 3, pp. 291-298 (1997). | | |
| | * | PCT/GB97/02362 - Scotia Holdings, PLC - Search Report - February 20, 1998 | | |
| | * | PCT/GB99/00563 - Scotia Holdings, PLC - Search Report - August 19, 1999 | | |
| | * | PCT/US00/06160 - Protarga, Inc. - Search Report - October 4, 2001 | | |
| | * | PCT/US00/12752 - Protarga, Inc. - Search Report - October 31, 2000 | | |
| | * | PCT/US89/00757 - Shashoua - Search Report - June 14, 1989 | | |
| | * | PCT/US91/03346 - Shashoua - Search Report - September 6, 1991 | | |
| | * | PCT/US97/08792 - Neuromedica, Inc. - Search Report - October 28, 1997 | | |
| | * | PCT/US97/08866 - Neuromedica, Inc. - Search Report - September 3, 1997 | | |
| | * | PCT/US97/08867 - Neuromedica, Inc. - Search Report - January 9, 1998 | | |
| | * | PCT/US98/24412 - Neuromedica, Inc. - Search Report - February 22, 1999 | | |
| | * | PCT/US98/24421 - Neuromedica, Inc. - Search Report - March 3, 1999 | | |
| | * | PCT/US98/24490 - Neuromedica, Inc. - Search Report - February 26, 1999 | | |
| | * | PCT/US99/01786 - Neuromedica, Inc. - Search Report - July 6, 1999 | | |
| | * | PONPIPOM, M.M. et al., "Structure-Activity Relationships of C1 and C6 Side Chains of Zaragozic Acid A Derivatives," <i>J. Med. Chem.</i> 1994, 37, pp. 4031-4051, XP-002311499. | | |
| | * | PUGLISI, G. et al., "Synthesis of Methotrexate γ,γ -Bis(Amides) and Correlation of Thermotropic and DPPC Biomembrane Interaction Parameters with Their Anticancer Activity," <i>Drug Development Research</i> 44, pp. 62-69 (1998), XP008039189. | | |
| | * | Rasmusson, Gary H., "Azasteroids: Structure-Activity Relationships for Inhibition of 5 β -Reductase and Androgen Receptor Binding," <i>J. Med. Chem.</i> , Vol. 29, pp. 2298-2315 (1986). | | |
| | * | RENTSCH, et al., "Pharmacokinetics of N ⁴ -Octadecyl-1- β -D-Arabinofuranosylcytosine in Plasma and Whole Blood after Intravenous and Oral Administration to Mice," <i>J. Pharm. Pharmacol.</i> 49 (1997), pp. 1076-1081. | | |
| | * | ROARK, W. H. et al., "Inhibitors of Acyl-CoA:Cholesterol Acyltransferase (ACAT). 2. Modification of Fatty Acid Anilide ACAT Inhibitors: Bioisosteric Replacement of the Amide Bond," <i>J. Med. Chem.</i> 1993, 36, pp. 1662-1668, XP002924002. | | |
| | * | SASSE, A. et al., "Development of Chiral N-Alkylcarbamates as New Leads for Potent and Selective H ₃ -Receptor Antagonists: Synthesis, Capillary Electrophoresis, and in Vitro and Oral in Vivo Activity," <i>J. Med. Chem.</i> 1999, 42, pp. 593-600, XP-002311502. | | |
| | * | SCOTT, et al., "Isolation and nucleotide sequence of cDNA encoding...", <i>Nature</i> 302, 538-540 (1983). | | |
| | * | SEKI, J., et al., "A nanometer lipid emulsion, lipid nano-sphere (LNS \oplus), as a parenteral drug carrier for passive drug targeting," <i>International Journal of Pharmaceutics</i> 273 (2004), pp. 75-83. | | |
| | * | SERGHERAERT, C. et al., "Synthesis and Anti-HIV Evaluation of D4T and D4T 5'-Monophosphate Prodrugs," <i>J. Med. Chem.</i> 1993, 36, pp. 826-830, XP-002311498. | | |
| | * | SHASHOUA, et al., "Evidence for the In Vivo Polymerization of Ependymin: Brain Extracellular Glycoprotein", <i>Brain Research</i> , 522, 181-190 (1990) | | |
| | * | SHASHOUA, V.E., "Ependymin, a Brain Extracellular Glycoprotein, and CNS Plasticity," reprinted from <i>Activity-Driven CNS Changes in Learning and Development</i> , vol. 627 of the Annals of the New York Academy of Sciences, Aug. 5, 1991). | | |

| | | | | | | | |
|----------------------------------|---|----|---|--------------------------------------|--|-----------------------------------|--|
| FORM PTO-1449/A and B (Modified) | | | | APPLICATION NO.: 10/618,884 | | ATTY. DOCKET NO.: N0260.70058US00 | |
| | | | | FILING DATE: July 14, 2003 | | CONFIRMATION NO.: 5880 | |
| | | | | APPLICANT: Victor E. Shashoua et al. | | | |
| | | | | GROUP ART UNIT: 1614 | | EXAMINER: Donna A. Jagoe | |
| Sheet | 7 | of | 7 | | | | |

OTHER ART — NON PATENT LITERATURE DOCUMENTS

| | | | | |
|--|---|---|--|--|
| | * | Shashoua, V.E., "The Role of Brain Extracellular Proteins...", <i>Cellular and Mol. Neurobiol.</i> , 5 (1/2):183-207 (1985). | | |
| | * | SHASHOUA, V.E., "The role of ependymin in the development of long lasting synaptic charges" <i>J. Physiol. Paris</i> , 83:232-239 (1988-1989) | | |
| | * | SIMONI, D. et al., "Geiparvarin Analogues. 2. Synthesis and Cytostatic Activity of 5-(4-Arylbutadienyl)-3(2H)-furanones and of N-Substituted 3-(4-Oxo-2-furanyl)-2-buten-2-yl Carbamates," <i>J. Med. Chem.</i> 1991, 34, pp. 3172-3176, XP-002311503. | | |
| | * | Smrt ^a , J., et al., "Synthesis of Some Nucleolipids." Collection Czechoslov. Chem. Commun., Vol. 45, pp. 927-931 (1980). | | |
| | * | Supplementary partial European search report from related European Patent Application EP 02731170.3, dated June 22, 2005 | | |
| | * | Supplementary Partial European Search Report in Application No. PCT/US02/09389, mailed January 5, 2005. | | |
| | * | TANAKA, T. et al., "Synthesis and Antioxidant Activity of Novel Amphipathic Derivatives of Tea Polyphenol," <i>Bioorganic & Medicinal Chemistry Letters</i> 8 (1998), pp. 1801-1806. | | |
| | * | TERASAWA, et al., "Neurocalcin" a novel calcium binding protein from bovine brain" <i>J. Biol. Chem.</i> , 267:27 (1992), pages 19596-19599 | | |
| | * | TSUSHIMA, S. et al., "Syntheses and Biological Activities of N-Alkyl- and N-Alkenylcarbamoyl Phospholipids," <i>Chem. Pharm. Bull.</i> 32(7): pp. 2700-2713 (1984), XP-002311500. | | |
| | * | Turesky, Samuel, et al., "In Vitro Chemical Inhibition of Plaque Formation." <i>J. Periodontol.</i> , Vol. 43, pp. 263-269 (1972). | | |
| | * | WASHBURNE, S. S. et al., "Isocyanates Derived from Fatty Acids by the Trimethylsilyl Azide Modification of the Curtius Rearrangement," <i>Journal of the American Oil Chemists' Society</i> , American Oil Chemists' Society, Champaign, U.S., vol. 49, 1972, pp. 694-695, XP008039249. | | |
| | * | YAMAMOTO et al., "The Survival of Rat Cerebral Cortical Neurons in the Presence of Trophic APP Peptides" <i>J. Neurobiol.</i> 25, 585-594 (1994). | | |
| | * | YOKOKAWA, et al., "The Synthesis of Rat Cerebral Cortical Neurons in the Presence of EF - Hand Type Calcium-Binding Peptides" <i>Chem. Lett.</i> 1627-1630 (1989). | | |
| | * | YOKOYAMA, K., et al., "Development of a corticosteroid incorporated in lipid microspheres (liposteroid)," <i>Drugs Exptl. Clin. Res.</i> XI(9) (1985), pp. 611-620. | | |
| | * | YOSHIDA, et al., "N ⁴ -Behenoyl-1-β-D-Arabinofuranosylcytosine(BH-AC) Pharmacokinetics" <i>Cancer and Chemical Treatment (Cancer and Chemotherapy)</i> 14(6) (1987), Part I pp. 1820-1824 - Japanese Language | | |
| | * | YOSHIDA, et al., "Pharmacokinetics of High Dose Treatments of N ⁴ -Behenoyl-1-β-D-Arabinofuranosylcytosine (BH-AC)" <i>Cancer and Chemical Treatment (Cancer and Chemotherapy)</i> 14(6) (1987), Part I pp. 1820-1824 - English Translation | | |
| | * | YOSHIDA, et al., <i>Cancer and Chemotherapy</i> 14(6) (1987), Part I pp. 1820-1824 - English Abstract | | |

| | | | |
|-----------|---|------------------|----------|
| EXAMINER: |  | DATE CONSIDERED: | 10/13/06 |
|-----------|---|------------------|----------|

#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. 10/107,537, filed March 25, 2002, and/or Serial No. 10/108255, filed March 25, 2002, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

[NOTE - The Office hereby waives the requirement under 37 CFR 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003 and for all international applications that have entered the national stage under 35 USC 371 after June 30, 2003. See 37 CFR 1.491(b). For all patent applications filed on or before June 30, 2003, copies of cited U.S. patents and patent application publications are still required unless an eIDS is filed. Copies of all other patent(s), publication(s), or other information listed must still be provided, even if it was previously submitted to, or cited by, the U.S. Patent Office in an earlier application, unless the earlier application is identified by the IDS and is relied upon for an earlier filing date under 35 U.S.C. §120, and the copy was provided in the earlier application.]